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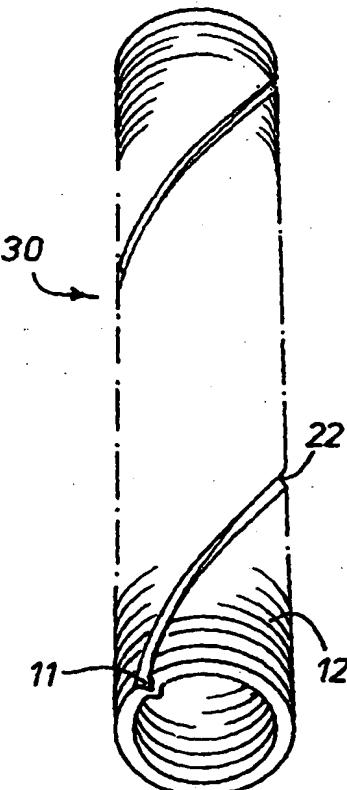
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(54) Title: A METHOD FOR INTRODUCING AN INTERNAL HELICAL FORMATION INTO A FLEXIBLE TUBULAR MATERIAL

(57) Abstract: There is disclosed a method for introducing a helical formation (11) into a flexible tubular material (12). The material (12) is supported together with a surrounding helical former (13) so as to deform the material (12) to have a helical indentation (11) corresponding to the shape of the former (13). The material (12) is then set in that configuration and the former (13) is removed.



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**A Method for Introducing an Internal Helical Formation into a
Flexible Tubular Material**

- 5 This invention relates to a method for introducing an internal helical formation into a flexible tubular member.

WO 00/38591 discloses the concept of helical formations in tubes for the purpose of improving in certain desirable respects, the flow of fluid through them.

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In particular, blood flow tubing, such as vascular grafts, can benefit markedly from internal helical formations such as ridges or grooves, which, if appropriately configured having regard to the tube dimensions and the density, viscosity and flow rate of blood therethrough, can eliminate turbulent flow and dead regions 15 which can lead to plaque formation, which, in turn, can lead to reduced flow capacity or thromboses.

However, one of the problems with implementing this is how to form the helical formation within the tube.

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In accordance with a first aspect of the invention, there is provided a method for introducing an internal helical formation into a flexible tubular material, the method comprising supporting the material on a mandrel having a groove, placing a helical former corresponding to the groove around the material so as to deform the 25 material to have an internal helical formation corresponding to the shape of the groove, setting the material in that configuration, and removing the former and the mandrel.

In accordance with a second aspect of the present invention, there is provided a 30 tube for a human or animal body, the tube comprising a flexible tubular material, a side wall of the tube being deformed to form a helical formation in the internal surface of the side wall of the tube.

The term "helical" as used herein covers the mathematical definition of helical and any combination of the mathematical definitions of helical and spiral.

The material is effectively clamped between the mandrel and the former.

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In one example, the material may be supported in a surrounding structure together with the former - the surrounding structure may comprise a cage such as a wire helix.

- 10 Whilst, as compared to the multi-start helical formulations proposed in WO 00/38591, the method of the present invention is particularly adapted to the introduction of a single start helical formation, it is found that such a formation is remarkable effective. Of course, the method of the invention could readily be adapted to the introduction of multi-start helical formations, if required, either by
- 15 having a multiple former arrangement or by using a single former repeatedly with an appropriate angular shift.

- Typically, the tubular material may be thermoplastic or thermosetting, and the material may be set by heat setting. Typically, the material is of a woven or knitted
- 20 structure in polyester. However, other materials such as PTFE and polyurethane, can be spun or extruded to the required shape.

- For vascular prostheses, it may be important to provide a degree of extensibility, so that the prosthesis may be under some tension between the anastomoses.
- 25 Any heat setting operation should leave the tubular material, therefore, still elastically extensible.

- 30 In order to provide the correct helix angle in a prosthesis in its tensional configuration, the material may be pre-tensioned for the introduction of the formation.

The material, after the formation has been set into it, may be coated with a bio-compatible dispersion, eg. with polyurethane. Typically, the former creates a

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groove in the external wide wall of the tubular material, and the dispersion is introduced into the groove in the external side wall. This helps to ensure that the internal formation maintains its shape.

5 Preferably, the dispersion is pressed into the material but typically does not penetrate the material to the inside surface. Preferably, the penetration is at least 50%, but less than 100%, and most preferably, 80% to 90% penetration.

A strand of a second material, which may have a different modulus of elasticity to
10 the tubular material, may be introduced into and secured in the external helical formation after the setting operation. The strand may be a monofilament or a multifilament strand. The strand may be secured by a subsequent coating.

The effect of the strand will be an extension of the finished prosthesis for implant,
15 to introduce a modular formation to the prosthesis, mimicking natural blood vessels.

Methods of introducing an internal helical formation into a flexible tubular material in accordance with the invention will now be described with respect to the
20 accompanying drawings, in which:

- Figure 1 is a view of a helical former for use in the method;
- Figure 2 is a view of a helically grooved mandrel for use in one method according to the invention;
- 25 Figure 3 is a cross-section through the mandrel of Figure 2, with the material and former in place;
- Figure 4 is a view of a cage, with former in place, in a second method according to the invention;
- Figure 5 is a cross-section of a helically deformed tube with a filament insert;
- 30 Figure 6 is a cross-sectional view of a tube after forming of the helical formation and having a polyurethane dispersion applied;

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- Figure 7 is a cross-section view of the tube of Figure 6 with a former being used to press the polyurethane dispersion into the material of the tube;
- 5 Figure 8 is an enlarged view of section A of Figure 7; and
- Figure 9 is a perspective view of a vascular graft manufactured using the method of the invention.

Figure 1 shows a helical former 13. Figure 2 shows a mandrel 14 having a helical groove 15 formed in the external surface of the mandrel 14. The helical shape 10 and cross-sectional shape of the former 13 corresponds to the helical shape and cross-sectional shape of the groove 15.

Figure 3 illustrates a method of using the former 13 and the mandrel 14 to form an internal helical formation 11 in a tubular material 12 to form a vascular graft 30 15 (see Figure 9). The tubular material 12 is supported on the mandrel 14 with the groove 15 corresponding to the configuration of the helical former 13. The material 12 is effectively clamped between the mandrel 14 and the former 13, and forced into the groove 15 by the former 13. For example, the mandrel 14 may be stainless steel and the former 13 may be PTFE.

20 Initially, the material 12 is placed on a straight (non-grooved) mandrel (not shown) and a thread is wound around the outside of the material 12. The ends of the material 12 are then pushed together so that the material 12 is concertinaed. The friction between the material 12 and the mandrel maintains the material in the 25 concertinaed configuration. The material 12 is then heat set at 95°C to 105°C for 3 to 4 hours. The thread may be removed before or after heat setting.

After this first heat set, the concertinaed material 12 is placed on to the mandrel 14 30 and the former 13 wound around the material, so that it engages with groove 15 in the mandrel 13 and the material 12 is clamped in the groove 15 between the mandrel 14 and the former 13. The material 12 is then heat set again at approximately 95°C to 105°C to set a helical formation 11 corresponding to the groove 15 and former 13.

Typically, before applying the former, tension is applied to the material 12 and this tension is maintained while the former 13 is wound around the material 12 and mandrel 14. Hence, during the second heat set, the material 12 is heat set with 5 pretension. This allows a degree of flexibility but helps prevent further extension of the material 12, which would change the helix angle of the helical formation 11. It also minimises the risk of graft movement or longitudinal extension post surgery.

After forming of the helical formation 11, a polyurethane dispersion 22 is applied 10 (see Figure 6) to the corresponding indentation on the external side wall of the material 12 by an applicator 20. A former 21 (see Figure 7) is then used to press the polyurethane into the material 12. However, the polyurethane 22 is not pressed by the former 21 so that it penetrates all the way through the material 12. Typically the penetration of the polyurethane 22 into the material 12 will be 15 approximately 80% to 90% of the thickness of the material 12. In addition, the amount of polyurethane 22 applied, the shape of the former 21 and the pressure applied by the former 21 are chosen such that the polyurethane 22 overflows the external indentation of the helical formation 11. In one example, the overflow, S, is approximately 2 mm to 3 mm over the edge of the indentation (see Figure 8).

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The material 12 is then removed from the mandrel 14 and the finished article can be used as a vascular graft 30 (see Figure 9) in the human or animal body.

Figure 4 illustrates an alternative method of forming the helical formation 11, in 25 which the material 12 is supported in a surrounding structure 16 together with the former 13. The surrounding structure 16 is in the form of a helical wire cage.

Although, in the example described above, heat setting is used in both the first and second settings of the material 12, any other setting method appropriate to the 30 material may be used. For example, appropriate setting methods may include chemical, infra-red or ultra-violet setting methods, or any method that initiates or effects cross-linking in a polymer is a possibility.

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However, it is desirable that, especially in the case of a vascular prosthesis, the finished product is elastically extensible, so as to be tensioned between the anastomoses. Generally, a tension resulting from a stretch of 10% of its maximum extensibility would be appropriate.

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- The correct helix angle of the indentation, namely the angle that gives, on theoretical, trial and error or whatever other appropriate grounds the best result in terms of the elimination of turbulent flow and dead flow areas in and downstream of the implant, the material 12 can be pre-stretched for the indentation by the 10%
10 or other appropriate amount without significantly altering the effectiveness of the indentation.

- 15 The material 12 may be coated, after the indentation, for any reason. It may be that the material, which may, for example, be a woven or knitted polyamide or polyester, is coated with a bio-compatible material such as a polyurethane.

- In another example (see Figure 5) a strand 17 may be incorporated into the indentation and sealed therein by the polyurethane dispersion 22 or by an overall coating, or a "local" coating or glue. The strand 17 may comprise a monofilament,
20 for example, of polyester, or it may be a multifilament strand. This can help to maintain the shape and integrity of the indentation, but can also have another effect, namely that on such extension as is required to give proper implant tension, the presence of the strand will imply an undulation to the tube, mimicking natural blood vessels.

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- Clearly, more than one helical "start" may be applied, as by having multiple helical formers or by applying a single such former two or more times each angularly displaced for all previous applications.

- 30 While the invention has been described particularly with reference to blood flow tubing and, more particularly, with regard to implants, it is possible to provide process plant pipework with internal spiral formations by similar means. In particular, if pipework is capable of deformation, it might well be given an internal

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helical formation by wrapping around it a helical former and pressing the former into the pipe, eg. by thermal contraction.

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CLAIMS

1. A method for introducing an internal helical formation into a flexible tubular material, the method comprising supporting the material on a mandrel having a groove, placing a helical former corresponding to the groove around the material so as to deform the material to have an internal helical formation corresponding to the shape of the groove, setting the material in that configuration, and removing the former and the mandrel.
- 10 2. A method according to claim 1, in which the material is supported in a surrounding structure together with the former.
3. A method according to claim 1 or claim 2, in which the material is thermoplastic or thermosetting and the material is set by heat setting.
- 15 4. A method according to any of the preceding claims, wherein the material is woven.
5. A method according to any of the preceding claims, wherein the material is knitted.
- 20 6. A method according to any of the preceding claims, in which the material is pre-tensioned during the introduction of the helical formation.
- 25 7. A method according to claim 6, in which the material is pre-tensioned to 10% of its maximum extensibility.
8. A method according to any of the preceding claims, in which a second material is applied to the material after the setting operation.
- 30 9. A method according to claim 8, wherein the former creates an indentation in the external side wall of the material and the second material is applied to the indentation.

- 9
10. A method according to claim 9, wherein the second material overflows the indentation.
11. A method according to any of claims 8 to 10, wherein the coating is a polyurethane dispersion.
12. A method according to any of claims 8 to 11, wherein the second material is pressed into the tubular material.
- 10 13. A method according to claim 12, wherein the second material does not penetrate the material to the internal side wall.
14. A method according to claim 13, wherein the second material penetrates at least 50% but less than 100% into the side wall of the material.
- 15 15. A method according to claim 14, wherein the second material penetrates 80% to 90% into the side wall.
16. A method according to any of the preceding claims, in which a strand of a third material having a different modulus of elasticity to the tubular material is introduced into and secured in the helical formation after the setting operation.
- 20 17. A method according to claim 16, in which the strand material comprises a monofilament.
- 25 18. A method according to claim 16, in which the strand material comprises a multifilament strand.
19. A method according to any of claims 16 to 18, in which the strand is secured by applying a coating to the tubular material.
- 30 20. A method according to any of the preceding claims, further comprising forming a concertinaed formation in the tubular material.

21. A tube for a human or animal body, the tube comprising a flexible tubular material, a side wall of the tube being deformed to form a helical formation in the internal surface of the side wall of the tube.

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22. A tube according to claim 21, the tube comprising an indentation in the external surface of the side wall, and a coating applied to the indentation.

23. A tube according to claim 22, wherein the coating penetrates the side
10 wall of the tube.

24. A tube according to claim 23, wherein the coating only partially penetrates the side wall.

15 25. A tube according to any of claims 22 to 24, wherein the coating comprises a polymeric material.

26. A tube according to claim 25, wherein the polymeric material comprises polyurethane.

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27. A tube according to any of claims 20 to 26, wherein the flexible tubular material is a woven material.

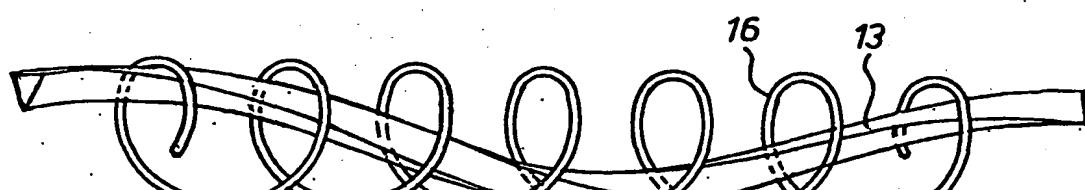
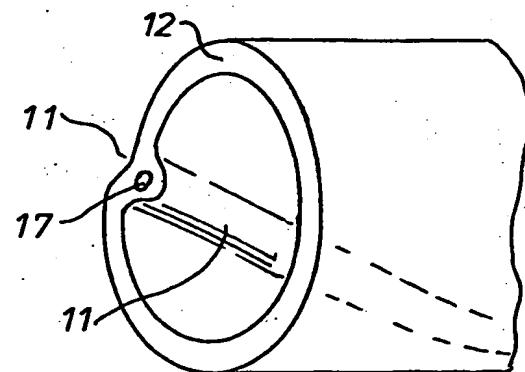
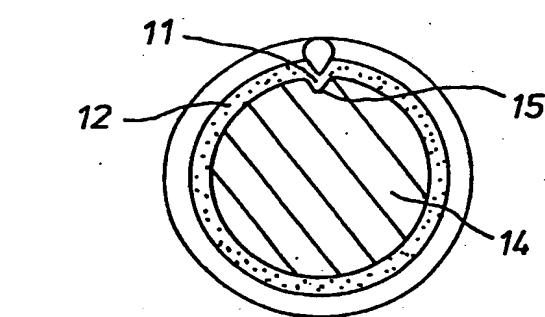
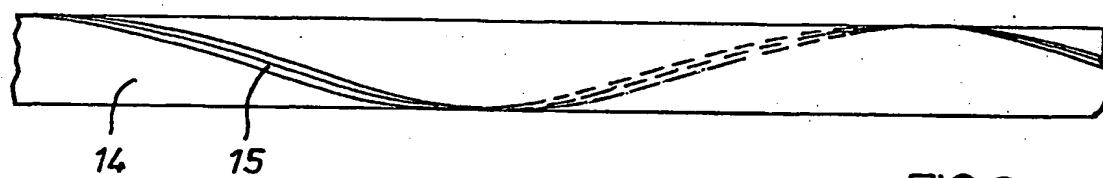
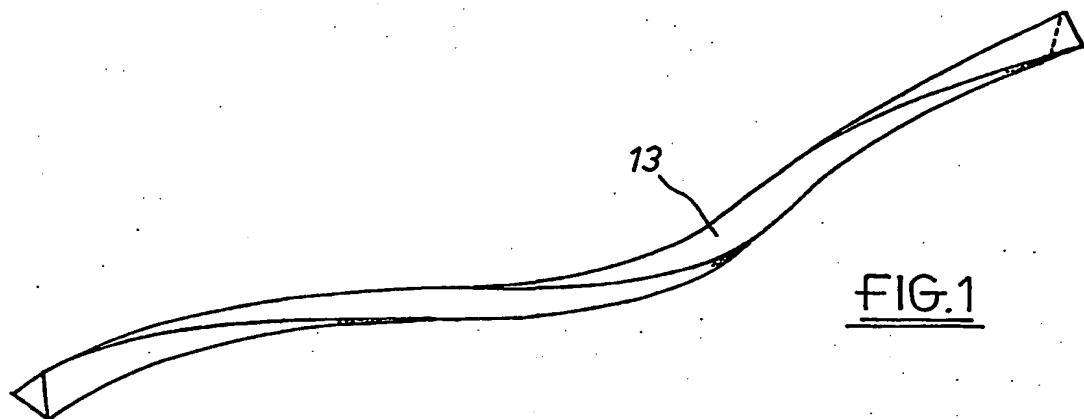
28. A tube according to any of claims 20 to 27, wherein the flexible
25 tubular material comprises polyester.

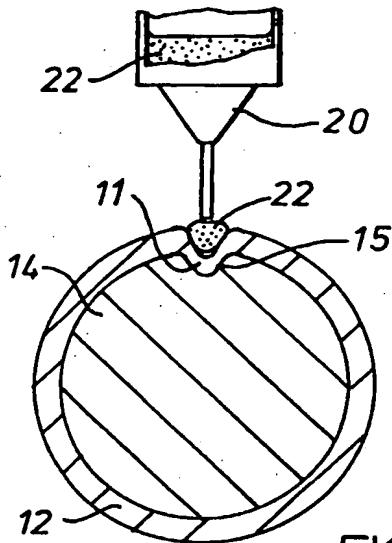
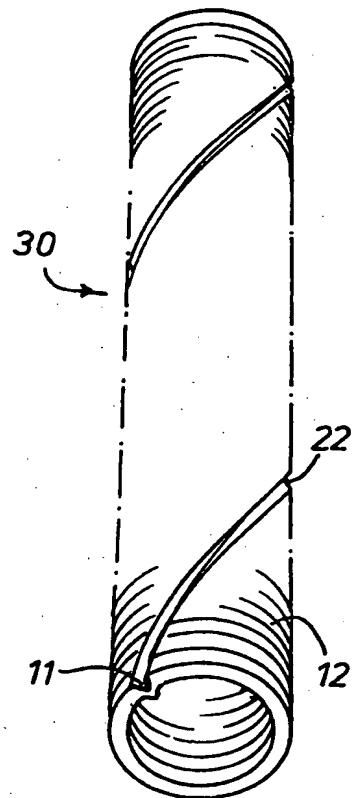
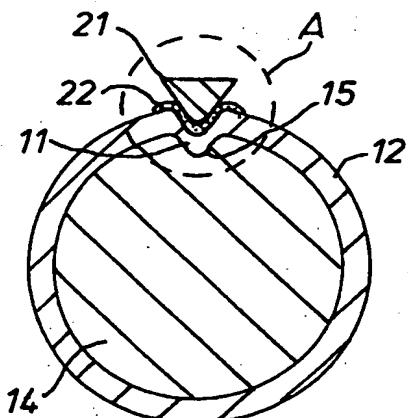
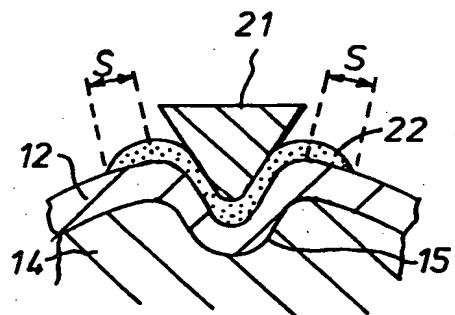
29. A tube according to any of claims 20 to 28, wherein the tube is blood flow tubing.

30 30. A tube according to claim 29, wherein the blood flow tubing is a graft.

31. A tube according to claim 30, wherein the graft is a vascular graft.

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FIG.6FIG.9FIG.7FIG.8

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER				
IPC 7 A61F2/06 F16L11/12 F15D1/06 B29C59/00 B29C59/02				
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched				
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
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A	---	1,4,5,20		
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A	---	1,22		
	-/-			
<input checked="" type="checkbox"/>	Further documents are listed in the continuation of box C.	<input checked="" type="checkbox"/>	Patent family members are listed in annex.	
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